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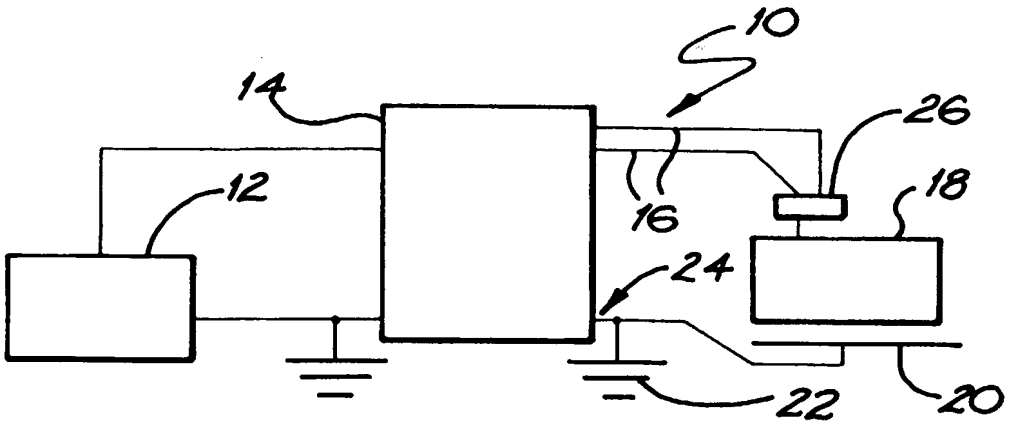
(54) Title: SYSTEM FOR, AND METHOD OF, HEATING A BIOLOGICAL SITE IN A PATIENT'S BODY



(57) Abstract: A system (10) for heating a biological site in a patient's body includes a transformer (14) having a primary winding and a secondary winding. The secondary winding has a tap (24) to provide a ground reference and two sources of radio frequency (RF) energy. An active electrode (16) is connected to each source to apply energy from its associated source to the site, the energy applied by one electrode (16) being out of phase with the energy applied by the other electrode (16).

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"System for, and method of, heating a biological site in a patient's body"

Field of the Invention

This invention relates to the heat treatment of a biological site in a human or animal body. More particularly, the invention relates to a system for, and method of, heating a biological site in a patient's body to produce at least one lesion at the site or for the treatment of pain management and to a component for use in the system.

Background to the Invention

Electromagnetic energy, in the form of radio frequency (RF) energy, is frequently used to produce lesions at a biological site in the human or animal body for many purposes such as, for example, for cardiac ablation purposes, for tumour ablation, etc. RF energy can also be used for heating a site for the treatment of pain management. To apply the RF energy at the required site in the body, an electrode is used as a conductor with an electrode tip forming a first terminal of the circuit and a backplate beneath the patient's body forming a ground electrode for the circuit so that, when the electrode tip is brought into contact with the site, a closed circuit is formed. A problem with this arrangement is that the impedance of the patient's body is high resulting in dissipation of the RF energy through the patient's body rather than being concentrated at the site.

Traditionally lesions have been produced at a site using a single active electrode system. The RF energy is applied to a small electrode tip towards the end of a catheter with an earth connection being made via the patient's body.

Summary of the Invention

According to a first aspect of the invention, there is provided a system for heating a biological site in a patient's body, the system including:

a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a ground reference and at least two sources of radio frequency (RF) energy; and

at least one active electrode connected to each source to apply energy from its associated source to the site, the energy applied by the at least one electrode of any one of the sources being out of phase with the energy applied by the at least one electrode of any of the other sources.

The system may include an energy generator for generating the RF energy, the primary winding of the transformer being connected to an output of the energy

generator. Instead, an impedance matching network may be used to facilitate use of existing equipment.

A reference, or indifferent, electrode may be connected to the at least one tap.

The transformer may have a 1:1 ratio between the primary winding and the secondary winding. Preferably, the tap is a centre tap to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other, but of equal amplitude, so that the total energy applied to the site is equivalent to the energy applied by a single electrode system.

At least one active electrode may be connected to a free end of each sub-winding opposite the end of the sub-winding connected to the tap.

Further, the system may use more than two electrodes. Then, a plurality of electrodes may be connected to the free end of each sub-winding, the electrodes of the sub-windings being arranged in groups relative to the site so that energy is applied across the site to effect heating of the site to produce a lesion or for pain management.

In addition, or instead, the secondary winding may have at least one intermediate tap between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources. At least one active electrode may be connected to each intermediate tap, the positions of the intermediate taps being selected to maintain sufficient potential difference between adjacent electrodes at the site, in use, to produce longer lesions.

While the system has been designed specifically for heating the site to an extent sufficient to cause the production of lesions in the heart for treatment of atrial fibrillation, the system may equally well be used for treatments of other forms of arrhythmia, for example, ventricular tachycardia. The electrodes may therefore be arranged transmurally, i.e. through a ventricular wall of the heart, for producing a transmural lesion at the relevant site to treat ventricular tachycardia. The system is also able to be used in the treatment of pain management where the site is heated to a temperature to ease discomfort caused by pain but insufficient to cause the production of lesions.

To facilitate mounting of the electrodes at the relevant site, in particular, in treating ventricular tachycardia, the at least one active electrode may be an electrode assembly comprising a co-axially arranged pair of electrodes, the electrodes of the assembly being displaceably arranged relative to each other. At least one of the electrodes may have a helical tip to be screwed into the site.

As a development of this arrangement, both electrodes of the assembly may be helical-tipped to be screwed into the site. The helical-tipped electrodes may be of

different pitches so that the depth into the site to which the electrodes extend, in use, differ with respect to each other.

According to a second aspect of the invention, there is provided a method of heating a biological site in a patient's body the method including the steps of:

providing a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a ground electrode and at least two sources of RF energy;

connecting at least one active electrode to each source; and

attaching the at least one active electrode from each source to the site and applying the energy from the sources to the site, the energy applied by the at least one electrode of any one of the sources being out of phase with the energy applied by the at least one electrode of any of the other sources.

The method may include providing an energy generator for generating the RF energy and connecting the primary winding of the transformer to an output of the generator. The transformer may be connected to the energy generator via an impedance matching network to facilitate use of existing equipment.

The method may include connecting a reference electrode to the at least one tap.

Further, the method may include selecting the transformer to have a 1:1 ratio between the primary winding and the secondary winding. The method may include centre-tapping the transformer to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase, but of equal amplitude, with respect to each other.

The method may include connecting at least one active electrode to a free end of each sub-winding opposite the end of the sub-windings connected to the tap. In addition, or instead, the method may include connecting a plurality of electrodes to the free end of each sub-winding and arranging the electrodes in groups relative to the site. Also, in addition, or instead, the method may include forming at least one intermediate tap between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources and connecting at least one active electrode to each intermediate tap, the positions of the intermediate taps being selected to maintain sufficient potential difference between adjacent electrodes at the site, in use, to produce longer lesions.

Still further, the method may include arranging the electrodes transmurally at the site for the treatment of particular forms of arrhythmia, eg, ventricular tachycardia. With this arrangement a transmural lesion is produced at the relevant site.

The method may include arranging the at least one active electrode as a co-axially arranged pair of electrodes, the electrodes of the pair being displaceably arranged relative to each other. The method may include providing at least one of the co-axially arranged pair of electrodes with a helical tip. Both electrodes of the co-axially arranged pair of electrodes may be helical-tipped and the method may include screwing the electrodes into the site to different depths to heat the site to the required depth. To facilitate this, the tips may be of different pitches.

The invention extends also to a component for use in heating a biological site in a patient's body, the component including a pair of co-axially arranged electrodes, at least one of which has a helical tip.

Preferably, both electrodes have helical tips. A pitch of one tip may differ with respect to a pitch of the other tip.

Brief Description of the Drawings

The invention is now described by way of example with reference to the accompanying drawings in which:

Figure 1 shows a block diagram of a system, in accordance with an embodiment of the invention, for heating a biological site in a patient's body;

Figure 2 shows a graph of various comparative waveforms;

Figure 3 shows a schematic representation of one embodiment of a component of the system of Figure 1;

Figure 4 shows a schematic representation of another embodiment of the component of the system of Figure 1; and

Figure 5 shows a block diagram of a system, in accordance with a second embodiment of the invention, for heating a biological site in a patient's body.

Detailed Description of the Drawings

Referring initially to Figure 1 of the drawings, a system, in accordance with an embodiment of the invention, for heating a biological site in a patient's body is illustrated and is designated generally by the reference numeral 10. The system 10 comprises a generator 12 for generating electromagnetic energy, more particularly, radiofrequency (RF) energy.

A transformer 14 is connected to an output of the RF generator 12. At least two active electrodes 16 are connected to outputs of the transformer 14, as will be described in greater detail below. By "active" is meant that, unless the context clearly indicates otherwise, the electrode is used to impart energy to the site.

The system 10 makes use of a patient's body as an impedance 18 and a closed circuit is formed by the use of a reference, or indifferent, electrode 20. The reference electrode 20 is tied to a ground 22 of the RF generator 12.

The transformer 14 is a centre-tapped transformer, a secondary winding of the transformer 14 having a centre tap 24 to form two separate sub-windings. The reference electrode 20 is connected to the centre tap 24. One of the active electrodes 16 is connected to an opposed, or free, end of each of the sub-windings of the transformer 14 formed by the centre tapping of the secondary winding. The transformer 14 may, optionally have intermediate taps(not shown) formed between the centre tap and each free end of each sub-winding. In that case, at least one active electrode may be connected to adjacent intermediate taps. The positions of the intermediate taps are selected to maintain sufficient potential difference between adjacent electrodes at the site to produce longer lesions.

The transformer 14 makes use of a 1:1 ratio between its primary winding and the secondary winding. Different ratios may be employed bearing in mind that, if a number of turns of the windings of the secondary winding are increased relative to that of the primary winding, the voltage across each secondary winding will increase with a corresponding decrease in current.

In addition, the materials used in the transformer 14 are selected to be capable of withstanding energy levels and frequencies involved in ablative therapies. The transformer 14 and the materials used are optimised to ensure maximum transfer of energy to the active electrodes 16.

Thus, suitable materials for the transformer 14 include nickel-zinc or manganese-zinc ferrites for a core of the transformer 14, in particular F8, F12, F14 ferrites. These materials are able to operate at the required frequencies and have the necessary high initial permeability and high saturation flux. It will be appreciated that dimensions of the core, number of turns of the windings and the diameter used for the windings are selected so that the transformer 14 has low insertion losses to ensure efficient transfer of energy.

The primary winding of the transformer 14 matches the output impendence of the generator. The generator 12 used in trials had an output impedance of between about 30 and 300 ohms. A series resistor and/or a parallel capacitor may be required to effect impedance matching.

The system 10 is designed particularly for use in the production of lesions at a site in a patient's body for treating various disorders such as atrial fibrillation, ventricular tachycardia, tumour ablation, pain management, etc. Traditionally, systems

for treatment of these disorders have used a single electrode with a backplate under the patient's body forming a return connection. This results in a large percentage of energy dissipation through the patient's body rather than being used for ablative purposes at the site in the patient's body.

With the provision of two active electrodes 16 in the system 10 of the present invention, an inter-electrode impedance, illustrated schematically at 26, is created between the active electrodes 16 resulting in greater energy transfer between the electrodes 16 rather than through the patient's body.

A representation of this is shown in Figure 2 of the drawings where waveform 28 is the voltage waveform of a single electrode of a prior art system. Voltage waveforms 30 and 32 are the 180° out of phase waveforms of each active electrode 16 of the system 10 of the present invention and waveform 34 is the sum of the absolute values of the amplitudes of the waveforms 30 and 32. Thus, it will be noted that the voltage between the electrodes 16, as represented by the waveform 34, is the same as the voltage of a single electrode 28 but that the energy is concentrated between the active electrodes 16 rather than between an electrode and any indifferent electrode relying on the patient's body.

It is to be noted that, in total, the energy of the system 10 is no higher than that of a prior art system as the energy applied to each active electrode 16 by the transformer 14 is half that applied to the single electrode of the prior art system.

The applicant believes that, with the concentration of energy between the active electrodes 16 of the present system 10, larger and deeper lesions may be formed between the two electrodes 16 than can be produced by a single electrode using the same RF energy. The reason for this is that the inter-electrode impedance 26 is much lower than that of the patient's body resulting in energy transfer between the electrodes 16 rather than dissipation of energy through the patient's body.

Table 1 below shows various tests which have been carried out experimentally.

No.	Notes	Spacing (mm)	Power (W)	Time (s)	Depth (mm)
1	2cath 2mm elect in phase	0	20	120	4
2	2cath 2mm elect out phase	0	20	120	3.5
3	2cath 2mm elect out phase	2	20	120	3.5
4	2cath 2mm elect out phase	5	20	120	6
5	2cath 2mm elect out phase	6.5	20	120	4.5
6	2cath 2mm elect out phase	9	20	120	5
7	2cath 2mm elect in phase (crossed)	0	20	120	No lesion

8	2cath 2mm elect in phase (crossed)	0	20	120	No lesion
9	2cath 2mm elect in phase	0	20	120	4
10	1cath 2mm	-	20	120	4.5
11	Three burn series (as 10) #1	-	20	120	5
12	Three burn series (as 10) #2	-	20	120	5
13	Three burn series (as 10) #3	-	20	120	5
14	2cath 2mm elect in phase	7	20	120	3.5
15	2cath pairs elect out phase (long elect)	4	20	120	6
16	2cath 4mm elect in phase	0	20	120	0.5
17	2cath 4mm elect out phase	0	20	120	6
18	2cath 4mm elect out phase	4	20	120	6
19	2cath 4mm elect out phase	7	20	120	8
20	2cath 4mm elect out phase	11	20	120	8
21	2cath 4mm elect in phase	0	20	120	0.5
22	2cath 4mm elect in phase	6	20	120	0.5
23	1 cath 4mm	-	20	120	5
24	2cath 4mm elect out phase transmural	-	20	120	13 - high damage
25	2cath 4mm elect out phase	4	10	120	5
26	2cath 4mm elect out phase	4	20	60	7
27	2cath 4mm elect out phase	4	20	30	5
28	2cath 4mm elect in phase transmural	-	20	120	6 - low damage

Table 1

A comparison between the various tests carried out shows that, with the provision of two electrodes relying on complementary and 180° out of phase energy, deeper lesions are formed. Reference is made particularly to tests 19 and 23 where it is to be noted that, with the use of the two active electrodes 16, a deeper lesion was formed than was the case with a single electrode.

Once again, comparing items 24 and 28, relating to transmural lesions, the use of the two out of phase electrodes 16 of the present system 10 (test 24) resulted in a significantly deeper lesion than using two electrodes in phase as shown by test 28.

To create a transmural lesion, particularly for the treatment of atrial fibrillation, one electrode may be placed thorascopically through the chest with a second electrode being inserted via a catheter inside the heart to achieve lesions through the heart wall.

Another approach contemplated for use with the present system 10 is the use of a component 30 comprising two, co-axially arranged electrodes for the treatment of ventricular tachycardia. In the embodiment shown in Figure 3 of the drawings, the

component 30 includes an inner electrode 32 which is a retractable electrode inserted via a catheter 34. The inner electrode 32 is screwed into position in tissue 36 at the site to be treated by means of a screw driver stylet (not shown) inserted through a lumen of the catheter 34 to extend the screw tipped electrode 32 relative to an outer, second electrode 38 into the tissue 36 of the heart wall. The second electrode 38, which may be fixed or retractable, is placed in contact with the endocardium of the heart to effect the production of a transmural legion 40.

The actual length of exposed metal of the screw electrode 32 can be optimised by insulating a portion of the screw. For example, the screw tip may be 20mm long but only the most distal 5mm is exposed metal. It will also be appreciated that the actual depth to which the electrode 32 is screwed into the tissue 36 of the heart wall is variable depending on the treatment required.

It will also be appreciated that the two electrodes 32, 38 are insulated from each other.

A variation of this arrangement is the use of two screw-tipped electrodes insulated from each other. This embodiment of the component is shown in Figure 4 of the drawings. With reference to Figure 3 of the drawings, like reference numerals refer to like parts unless otherwise specified.

In this embodiment, both electrodes 32 and 38 are screw-tipped or helical-tipped. The screw tip of the inner electrode 32 has a larger pitch than the outer electrode 38. Hence, when the electrodes 32, 38 are extended out of the catheter 34, the electrode 32 is screwed into the tissue 36 of the heart wall to a greater depth than the electrode 38. The finer pitched, outer electrode is urged into contact with the endocardium. Once again, screw depth can be optimised depending on the depth of the conductive fibres causing the arrhythmia.

The applicant is of the view that the use of concentric electrodes, in particular, would be useful for the treatment of ventricular tachycardia but could be of use in other applications as well.

In another embodiment of the invention, the transformer 14 of the system 10 has multiple taps in its secondary winding. This embodiment of the invention is illustrated schematically in Figure 5 of the drawings. With reference to Figure 1 of the drawings, like reference numerals refer to like parts, unless otherwise specified.

Hence, the transformer 14 has a primary winding 14.1 and a secondary winding 14.2 wound about a core 14.3. The core 14.3 is made from one of the materials referred to above. The secondary winding 14.3 has the centre tap 24 and an intermediate tap 42 connected between each end tap 44 and the centre tap 24.

An active electrode 16 is connected to each tap 42 and 44 and the ground electrode 20 is connected to the centre tap 24. The signals provided to each electrode 16 on the same side of the centre tap 24 are in phase but are at a predetermined potential difference relative to each other and to the centre tap 24. The value of this potential difference is governed by the number of turns of the secondary winding. The signals provided to the taps 42 and 44 and, hence, the electrodes 16 connected to those taps 42 and 44, on one side of the centre tap 24 are 180° out of phase with the signals provided to the taps 42 and 44 and, hence, their associated electrodes 16, on the other side of the centre tap.

With the provision of the intermediate taps 42, a greater surface area of the site can be heated. Hence, where the site is undergoing heating to create lesions, longer lesions are formed as a result of using the electrodes 16 connected to the intermediate taps 42 in addition to the electrodes 44 connected to the end taps 44.

Optimisation of the system 10 involves the positioning of the tap 24 on the secondary winding of the transformer 14 as well as the shape and size of the electrodes 16. To reduce charring at the site, the electrodes connected to the sub-windings of the secondary winding may be arranged in groups, for example, pairs. By placing the electrodes in groups, each electrode may impart lower energy to the site thereby reducing the likelihood of charring. In addition, use of multiple electrodes can be used for pain management with the RF energy being delivered through at least two of the electrodes simultaneously. The positioning of two electrodes may be less dangerous than a single electrode with an earth electrode. For example, in pain management where energy is applied to a patient's spine, placing an electrode on each side of the spine rather than one directly into the spine may be less risky. It will be appreciated that, for pain management, no ablating occurs and the electrodes are therefore operated at power levels insufficient to cause ablation of the tissue.

In addition, for ablating a tumour, by placing the electrodes 16 on opposite sides of the tumour, more mass of the tumour can be ablated than with the use of a single electrode.

Accordingly, it is an advantage of the invention that a system 10 and method are provided where, due to energy transfer between the active electrodes 16, deeper lesion production and more accurate lesion production is facilitated. In addition, the use of a pair of active electrodes reduces the risks involved in the production of lesions for treatment of various disorders.

The use of at least two active electrodes is of significant benefit in creating linear lesions such as used in "Maze-like" procedures as well as in the production of transmural lesions which are beneficial in treating ventricular tachycardia.

Another major benefit of the system 10 is the use of a centre-tapped transformer to provide the out of phase energy sources. The centre tapped transformer considerably reduces the complexity of the system 10 as the need for complicated and expensive control circuitry is obviated. The transformer 14 provides the energy sources in a simple but reliable way. The use of the transformer 14 also obviates the need for complex set-up procedures. In effect, the transformer 14 need only be connected to the generator 12, the electrodes 16 positioned and the system 10 is ready for use. No complicated calibration or training procedures are required to use the system 10.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A system for heating a biological site in a patient's body, the system including:

a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a ground reference and at least two sources of radio frequency (RF) energy; and

at least one active electrode connected to each source to apply energy from its associated source to the site, the energy applied by the at least one electrode of any one of the sources being out of phase with the energy applied by the at least one electrode of any of the other sources.

2. The system of claim 1 which includes an energy generator for generating the RF energy, the primary winding of the transformer being connected to an output of the energy generator.

3. The system of claim 1 or claim 2 in which a reference electrode is connected to the at least one tap.

4. The system of any one of the preceding claims in which the transformer has a 1:1 ratio between the primary winding and the secondary winding.

5. The system of any one of the preceding claims in which the tap is a centre tap to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

6. The system of claim 5 in which at least one active electrode is connected to a free end of each sub-winding opposite the end of the sub-winding connected to the tap.

7. The system of claim 6 in which a plurality of electrodes are connected to the free end of each sub-winding, the electrodes being arranged in groups relative to the site.

8. The system of claim 6 or claim 7 in which the secondary winding has at least one intermediate tap between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources with at least one active electrode being connected to each intermediate tap.

9. The system of any one of the preceding claims in which the at least one active electrode is an electrode assembly comprising a co-axially arranged pair of electrodes, the electrodes of the assembly being displaceably arranged relative to each other.

10 The system of claim 9 in which at least one of the electrodes has a helical tip to be screwed into the site.

11. The system of claim 10 in which both electrodes of the assembly are helical-tipped to be screwed into the site.

12. The system of claim 11 in which the helical-tipped electrodes are of different pitches so that the depth into the site to which the electrodes extend, in use, differ with respect to each other.

13. A method of heating a biological site in a patient's body the method including the steps of:

providing a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a ground reference and at least two sources of RF energy;

connecting at least one active electrode to each source; and

attaching the at least one active electrode from each source to the site and applying the energy from the sources to the site, the energy applied by the at least one electrode of any one of the sources being out of phase with the energy applied by the at least one electrode of any of the other sources.

14. The method of claim 13 which includes providing an energy generator for generating the RF energy and connecting the primary winding of the transformer to an output of the generator.

15. The method of claim 13 or claim 14 which includes connecting a reference electrode to the at least one tap.

16. The method of any one of claims 13 to 15 which includes selecting the transformer to have a 1:1 ratio between the primary winding and the secondary winding.

17. The method of any one of claims 13 to 16 which includes centre-tapping the transformer to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

18. The method of claim 17 which includes connecting at least one active electrode to a free end of each sub-winding opposite the end of the sub-winding connected to the tap.

19. The method of claim 18 which includes connecting a plurality of electrodes to the free end of each sub-winding and arranging the electrodes in groups relative to the site.

20. The method of claim 18 or claim 19 which includes forming at least one intermediate tap between the ground reference tap and the free end of each sub-winding to provide more than two sub-windings acting as energy sources and connecting at least one active electrode to each intermediate tap.

21. The method of any one of claims 18 to 20 which includes arranging the electrodes transmurally at the site.

22. The method of any one of claims 18 to 21 which includes arranging the at least one active electrode as a co-axially arranged pair of electrodes, the electrodes of the pair being displaceably arranged relative to each other.

23. The method of claim 22 which includes providing at least one of the co-axially arranged pair of electrodes with a helical tip.

24. The method of claim 23 in which both electrodes of the co-axially arranged pair of electrodes are helical-tipped and in which the method includes screwing the electrodes into the site to different depths to heat the site to the required depth.

25. A component for use in heating a biological site in a patient's body, the component including a pair of co-axially arranged electrodes, at least one of which has a helical tip.

26. The component of claim 25 in which both electrodes have helical tips.

27. The component of claim 26 in which a pitch of one tip differs with respect to a pitch of the other tip.

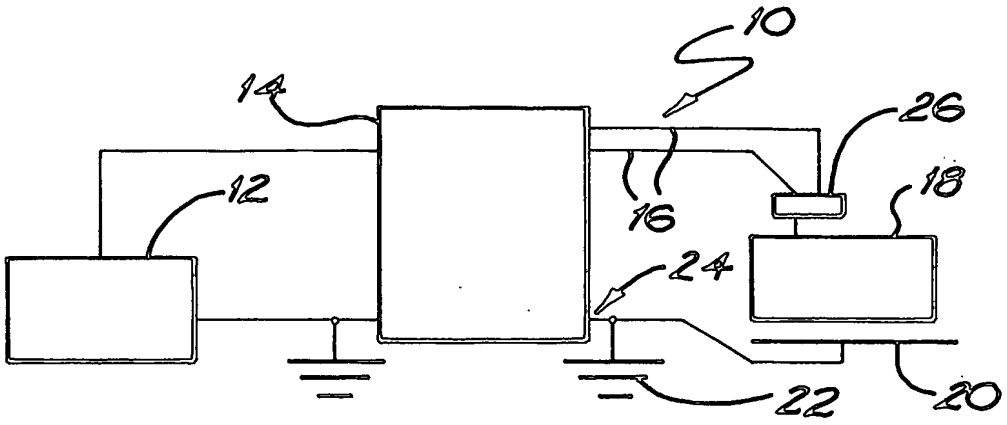
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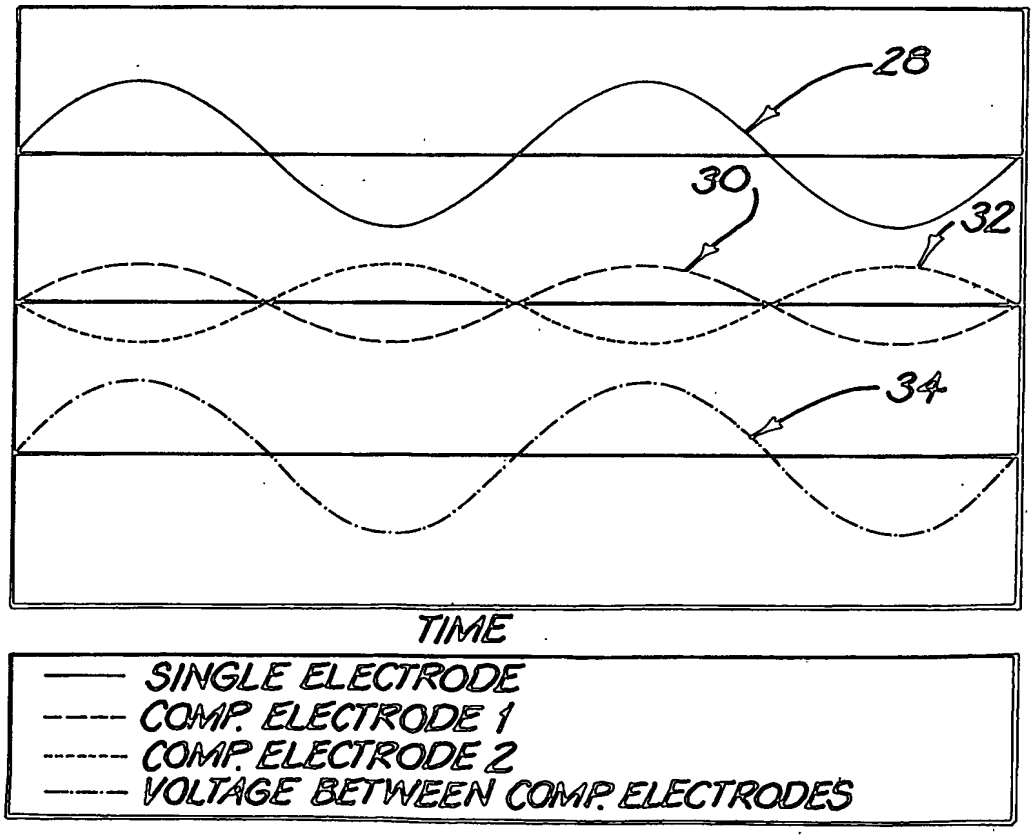
FIG. 1


28
30
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VOLTAGE BETWEEN COMP. ELECTRODES

FIG. 2

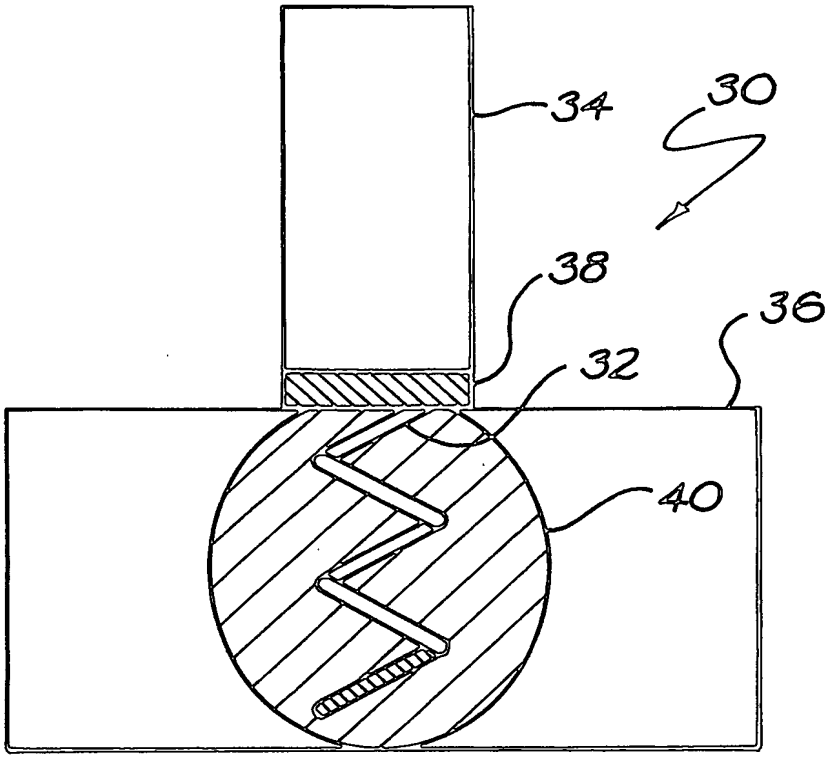

FIG. 3

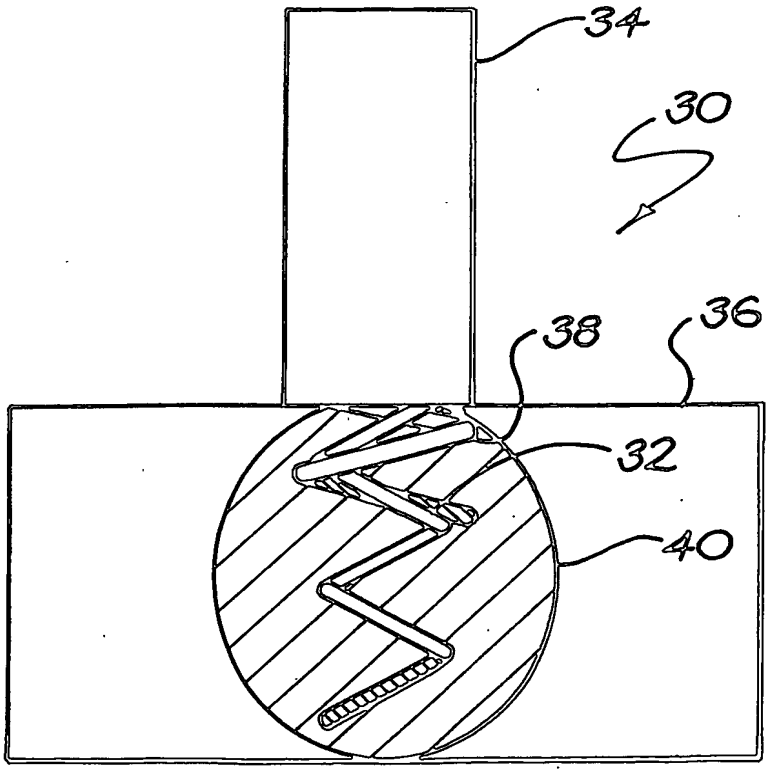

FIG. 4

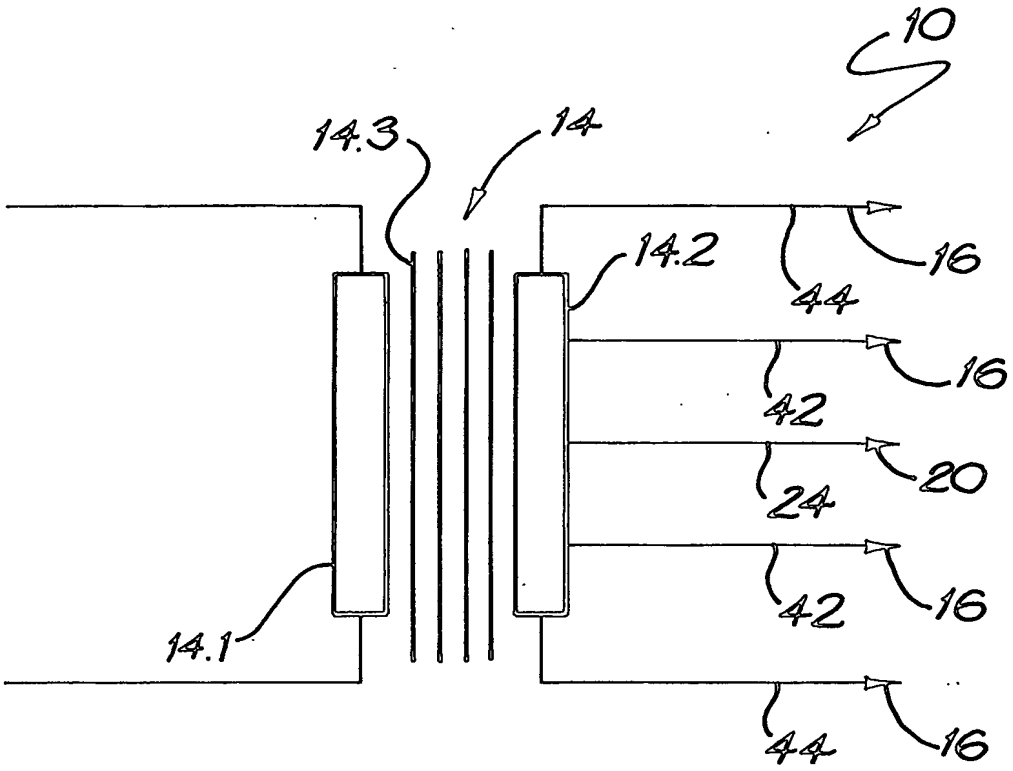

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2003/001421

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61B 18/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
REFER TO THE ELECTRONIC DATABASE CONSULTED BELOW

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI + key words(a61b, a61f, a61n, heat, ablate, rf, radiofrequency, phase etc)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5693078 A (DESAI et al) 2 December 1997 See entire document	1-24
A	US 5697928 A (WALCOTT et al) 16 December 1997 See entire document	1-24
A	WO 1995/025472 A1 (VIDAMED, INC) 28 September 1995 See entire document	1-24

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 January 2004	02 FEB 2004
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	SWAYAM CHINTAMANI Telephone No : (02) 6283 2202

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2003/001421

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet...

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-24**

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2003/001421

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-24 relate to a system for heating a biological site comprising a transformer and active electrodes connected to at least two sources of radio frequency energy. It is considered that the energy applied by one electrode being out of phase with energy applied by another electrode of any other source of energy comprises a first "special technical feature".

2. Claims 25-27 are directed to a component for use in heating a biological site. It is considered that the component including a pair of coaxially arranged electrodes, at least one of which has a helical tip, comprises a second "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

Furthermore, the groups of claims have distinct classifications under the IPC and therefore it is considered that because of these distinct classifications, constitute separate search areas, these inventions could not be searched without involving significant extra effort.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU2003/001421

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5693078	AU	22485/92	CA	2112821	EP	0598742
		EP	0904800	EP	1382368	JP	2002238917
		MX	9203954	US	5383917	US	5620481
		US	2001051803	US	2003199868	WO	9300958
US	5697928	CA	2264826	EP	1011496	WO	9811938
WO	9525472	AU	10858/92	AU	11602/97	AU	11795/95
		AU	14036/95	AU	14476/95	AU	15278/97
		AU	15602/95	AU	19686/97	AU	19895/97
		AU	20475/95	AU	20708/97	AU	21355/97
		AU	21916/97	AU	21965/95	AU	22782/97
		AU	24621/97	AU	28717/95	AU	29981/95
		AU	30774/97	AU	31195/97	AU	31413/97
		AU	31455/97	AU	32040/97	AU	32951/95
		AU	34022/97	AU	46465/97	AU	47650/96
		AU	49998/93	AU	57192/01	AU	61331/94
		AU	61896/98	AU	68190/94	AU	68234/94
		AU	68506/96	AU	68514/96	AU	68988/96
		AU	69087/94	AU	69548/96	AU	70078/96
		AU	70565/94	AU	78099/98	AU	85702/98
		BR	9306893	CA	2061215	CA	2121032
		CA	2155217	CA	2162724	CA	2162887
		CA	2193964	CA	2226484	CA	2252461
		CA	2252820	CA	2253617	CA	2253705
		CA	2253847	CA	2266590	CN	1119418
		CN	1125390	CN	1128943	CN	1216911
		CN	1217639	CN	1219885	DE	4305663
		DE	4416840	DE	4416902	DE	4423216
		DE	4423228	EP	0521595	EP	0611314
		EP	0628288	EP	0629382	EP	0631514
		EP	0637436	EP	0667126	EP	0697837
		EP	0729321	EP	0767629	EP	0790066
		EP	0850023	EP	0893101	EP	0901348

EP	0901398	EP	0904025	EP	0914068
EP	0925042	EP	0935444	EP	0949890
EP	0957796	EP	0959785	EP	1001710
FI	950584	FR	2694700	FR	2705241
FR	2705242	FR	2709065	FR	2716365
GB	2269538	IL	104647	IL	108532
IL	109544	IL	109545	JP	7255855
KR	2000010722	KR	2000010723	KR	2000010815
MX	9304905	NL	1000670	NL	1003812
NZ	255687	US	5228441	US	5315996
US	5322064	US	5329923	US	5366490
US	5370675	US	5385544	US	5409453
US	5421819	US	5435805	US	5454787
US	5456662	US	5470308	US	5470309
US	5477856	US	5484400	US	5486161
US	5505730	US	5514131	US	5531676
US	5531677	US	5536240	US	5540655
US	5542915	US	5542916	US	5549644
US	5554110	US	5556377	US	5558672
US	5569241	US	5573774	US	5575788
US	5582589	US	5591125	US	5599294
US	5599295	US	5607389	US	5630794
US	5667488	US	5672153	US	5674191
US	5681277	US	5681308	US	5685839
US	5685868	US	5707349	US	5718702
US	5720718	US	5720719	US	5728094
US	5730719	US	5738114	US	5741225
US	5743870	US	5743904	US	5746224
US	5749846	US	5762626	US	5769846
US	5800378	US	5800379	US	5800429
US	5807308	US	5807309	US	5817049
US	5820580	US	5823197	US	5827273
US	5827277	US	5836906	US	5843021
US	5843026	US	5843077	US	5848986
US	5865788	US	5869503	US	5869505
US	5879349	US	5895370	US	5921954
US	5964727	US	5964755	US	5972974

US	6002968	US	6006755	US	6009877
US	6022334	US	6024743	US	6044846
US	6056744	US	6077257	US	6092528
US	6102886	US	6126657	US	6129726
US	6152143	US	6179803	US	6206847
US	6210355	US	6241702	US	6254598
US	6302898	US	6315776	US	6405732
US	6416491	US	6419673	US	6610054
US	2001011161	US	2001031941	US	2001034518
US	2001051783	US	2002091381	US	2002103483
US	2002115991	US	2002183735	US	2002183740
US	2003109866	US	2003144659	WO	0176495
WO	0180723	WO	9404220	WO	9417856
WO	9426178	WO	9426186	WO	9426187
WO	9505124	WO	9513752	WO	9517132
WO	9518575	WO	9519142	WO	9600041
WO	9600042	WO	9622742	WO	9706738
WO	9706741	WO	9726836	WO	9730644
WO	9730645	WO	9730646	WO	9730647
WO	9741785	WO	9741786	WO	9741787
WO	9741788	WO	9741789	WO	9743969
WO	9743970	WO	9743971	WO	9743972
WO	9743973	WO	9744092	WO	9801087
WO	9811834	WO	9820814	WO	9903412
WO	9907299				

END OF ANNEX